Dorian S. Berger, CA State Bar No. 264424
Daniel P. Hipskind, CA State Bar No. 266763
OLAVI DUNNE LLP
1880 Century Park East, Ste. 815
Los Angeles, California 90025
Telephone: 213-516-7900
Facsimile: 213-516-7910
Email: dhipskind@olavidunne.com
Email: dberger@olavidunne.com

Tom Myers, CA State Bar No. 176008
Arti L. Bhimani, CA State Bar No. 235240
Liza M. Brereton, CA State Bar No. 261380
AIDS HEALTHCARE FOUNDATION
6255 W. Sunset Blvd., 21st Fl.
Los Angeles, California 90028
Telephone: 323-860-5200
Facsimile: 323-467-8450
Email: Tom.Myers@aidshealth.org
Email: Arti.Bhimani@aidshealth.org
Email: Liza.Brereton@aidshealth.org

Attorneys for Plaintiff AIDS Healthcare Foundation, Inc.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

AIDS HEALTHCARE FOUNDATION, INC., Plaintiff, **v.** **GILEAD SCIENCES, INC.;** **JAPAN TOBACCO, INC.;** **JAPAN TOBACCO INTERNATIONAL U.S.A., INC.; AND** **EMORY UNIVERSITY,** Defendants	**Case No. :_____** **COMPLAINT FOR DECLARATORY JUDGMENT OF PATENT INVALIDITY AND VIOLATION OF THE SHERMAN ACT, 15 U.S.C. §§ 1 & 2** **JURY TRIAL DEMANDED**

AIDS Healthcare Foundation ("AHF"), the largest non-profit provider of specialized HIV/AIDS medical care in the United States brings this action to stop Gilead Sciences, Inc. ("Gilead") from blocking affordable access to a lifesaving HIV drug - Tenofovir Alafenamide ("TAF").

I. INTRODUCTION

1. In a relentless effort to maximize its profits, Gilead manipulated the patent system and engaged in anticompetitive practices to prevent economical access to TAF – an antiviral agent used in the treatment of HIV. TAF is not a new compound. TAF is a prodrug[1] of the compound Tenofovir, which was first synthesized over thirty years ago in the Czech Republic. Nor was TAF the first prodrug of Tenofovir. Several years before Gilead obtained a patent on TAF, Gilead had patented a similar prodrug called Tenofovir Disoproxil ("TDF"). Despite similarities between TAF and TDF and the weakness of the patents covering TAF, Gilead illegally seeks to extend the period of patent exclusivity for drugs incorporating Tenofovir by decades.

2. Gilead's attempt to extend the period of patent exclusivity for drugs incorporating Tenofovir arises from Gilead manipulating the patent system, entering into a licensing agreement with Japan Tobacco, and using a preexisting patent licensing agreement with Emory University to block entry by potential competitors and prevent competition. Gilead's actions have directly harmed AHF, which in 2015 alone purchased millions of dollars of antiviral drugs from Gilead.

3. In the first three quarters of 2015, Gilead sold over fifteen billion dollars of HIV antiviral drugs in the United States. Roughly 80% of these drugs incorporate a prodrug of Tenofovir called Tenofovir Disoproxil ("TDF"). TDF and TAF are both prodrugs and very closely related. The patents on TDF expire in 2017 and 2018. The impending expiration of the TDF patents presented a financial challenge to Gilead, as Gilead was heavily reliant on the patent exclusivity period of the TDF patents to prevent entry by generic pharmaceutical makers. The expiration of the TDF patents would leave Gilead with no patent exclusivity relating to Tenofovir, as the compound patent had expired and the prodrug formulation (TDF) was about to expire.

[1] Prodrugs are medicines that are converted into their active form once they are processed inside the body. In the case of TAF, it is taken orally and after absorption it passes into the blood.

Instead of allowing the patents to expire and generics to enter the market, thus helping to lower the prices of necessary medications for HIV patients, Gilead developed a complex, anticompetitive scheme to extend its exclusivity on drugs incorporating Tenofovir.

4. ***First***, Gilead did not conduct clinical trials in humans using TAF until 2011 despite presenting test tube and animal data on the use of TAF ten years prior. By waiting to take TAF to clinical trial just years prior to TDF's patent expiration (December 2017), Gilead was able to extend patent protection on Tenofovir by six years, and potentially longer if Gilead seeks additional patents on formulations and methods of use. Had Gilead not delayed in bringing TAF to clinical trials, Gilead's patent exclusivity on TAF would be significantly shorter. The delay in conducting clinical trials deprived those suffering from HIV of TAF for more than a decade. These people suffering with HIV were forced to take TDF, which because of TDF's lower absorption rates had higher bone and kidney toxicities.[2] It is possible that HIV patients suffered from 10 years of additional accumulated kidney and bone toxicity using TDF while TAF stayed on the shelf.

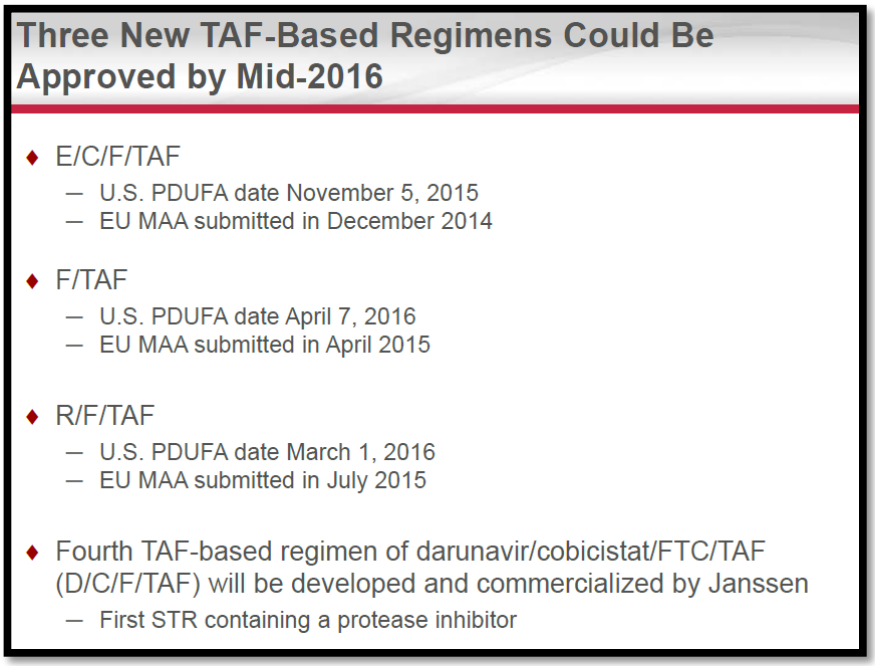
5. ***Second***, Gilead sought patent protection on another prodrug formulation of Tenofovir that would have been obvious at the time. Given the existing prior knowledge for formulating antiviral compounds as prodrugs to allow intracellular absorption, substituting the disoproxil ester of Tenofovir with an aryl phosphoramidate ester was an obvious substitution. Similarly, the use of fumarate salt for formulation purposes was obvious in light of Gilead's already patented TDF prodrug. The patents Gilead has sought and been granted, despite being invalid under 35 U.S.C. §§101-103, allow Gilead to exclude generic competition if they remain unchallenged. The TAF patents also have extended by at least seven years the patent exclusivity period that Gilead has for drugs incorporating Tenofovir to combat HIV.

6. Patent expiration dates are critical to preserving the price of a drug. Internal

[2] Gilead's Chairman and CEO John Martin has trumpeted the superior safety of TAF over TDF as a reason for customers to switch. "[TAF] has a superior safety profile compared to TDF. This is important because most newly diagnosed patients will now be treated for decades, and at the same time, many HIV-infected individuals who are in treatment, particularly in the U.S. and Europe, are advancing in age." Q2 2015 Gilead Earnings Call (Jul 29, 2015).

documents from Gilead have shown that revenues on a drug going off patent decay 20% the first year and 50% per year for the following three years.[3] AHF seeks a declaratory judgment that the patents covering TAF are invalid.

7. Gilead's refusal to make TAF available as a standalone drug appears to be a calculated, anticompetitive maneuver aimed at keeping competing TAF drugs off the market for years despite the weakness of Gilead's patents covering TAF. Gilead has and continues to make TDF available as a standalone product under the brand drug Viread. Viread's only active ingredient is TDF, and Gilead has repeatedly stated that TAF is an alternative to TDF whose significant difference is that it is absorbed more efficiently and thus avoids bone and kidney toxicity. The failure to make TAF available as a standalone drug highlights Gilead's motive of avoiding competition at all costs.



Gilead Third Quarter Earnings Slides, GILEAD FINANCIAL PRESENTATION at 12 (October 27, 2015) (showing that Gilead intends to offer TAF only in combination with other drugs. This allows Gilead to hide behind comparatively stronger patents of the other drugs included in the combination products and avoid potential challenges to the weak TAF patents.).

8. ***Third***, Gilead has entered into licensing agreements with Japan Tobacco and Emory University to develop and sell compound drugs that enjoy the patent protections of not

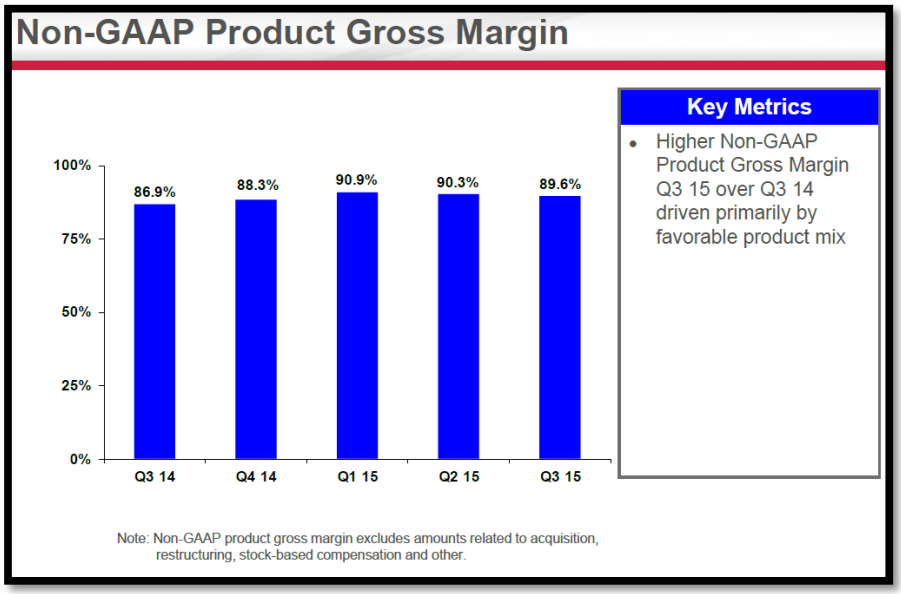
[3] Gilead Project Harry – Model Discussion GS-0005534 (August 16, 2011).

only the TAF patents, but also the patents that cover the other pharmaceutical compounds in these combination drugs. Further, Gilead has failed to make TAF available in a standalone drug where its weak patents would be challenged. Under the Hatch-Waxman regulatory regime, a generic manufacturer entering the market would have to invalidate the TAF patents as well as the patents that cover the three other compounds in the combination drug. Gilead has tactically chosen to not offer a standalone TAF drug so that any generic maker entering the market would be forced to either challenge 12 patents covering four separate pharmaceutical compounds, or go through the years-long and incredibly expensive process of conducting clinical trials.

9. Gilead's November 2015 release of the brand drug Genvoya (which incorporates TAF) is indicative of the anti-competitive strategy employed by Gilead to protect TAF from a patentability challenge directly. Genvoya is a fixed-dose combination tablet containing elvitegravir, cobicistat, emtricitabine, and TAF. Because Genvoya contains three compounds in addition to TAF, Gilead is able to list twelve patents as covering Genvoya in the FDA's Orange Book. A generic wishing to enter the market (pursuant to Hatch-Waxman regulations) has to prove non-infringement or invalidity of twelve patents versus the three weak patents that are specific to TAF. Gilead, by entering into exclusive license agreements with Japan Tobacco and Emory and illegally tying the availability of TAF to compounds such as elvitegravir and emtricitabine, has engaged in a conspiracy in restraint of trade in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2.

10. Gilead's tactics have allowed Gilead to reap outsized profits, and if allowed to continue, will harm the public and AHF. In 2015, Gilead was able to earn 90% Non-GAAP Product Gross Margins. Gilead's tactics led the New York Times to comment, "Gilead now is faced with figuring out ***what to do with all the cash it is generating***."[4]

[4] Andrew Pollack, *Sales of Solvadi, New Gilead Hepatitis C Drug, Soar to $10.3 Billion,* NY TIMES (February 4, 2015) (emphasis added).



Gilead Third Quarter Earnings Slides, GILEAD FINANCIAL PRESENTATION at 39 (October 27, 2015).

11. By maintaining exorbitant pricing for antiviral drugs, Gilead can rely on gamesmanship to avoid competition rather than expending money on research and development of new drugs. Gilead, in its 2015 Guidance stated that it anticipated spending between 2.8 and 3 billion dollars on research and development, while earning a profit of roughly 23 billion dollars.[5]

12. The high prices of antiviral drugs impact the availability of these lifesaving drugs for the public. High prices of drugs such as Gilead's Genvoya ($31,362 per year) limit patient access either through exorbitant co-pays, limitations in existing insurance, and rationing of these high priced pills. The high price of Gilead's Hepatitis C treatment has led many state Medicare programs to limit the number of infected people who will actually receive treatment. High prices have forced Medicare patients to wait indefinitely for access to Gilead's drug while continuing to suffer the effects of Hepatitis C, including liver failure, liver cancer, and blood disorders. Gilead's pricing of its Hepatitis C drug led to a United States Senate Investigation in 2015 and the release of a report that found, "It was always Gilead's plan to maximize revenue, and affordability and accessibility was an afterthought."[6]

---

[5] Gilead Guidance for 2015, Q3 2015 Earnings Slides at 2 (October 27, 2015).

[6] Bill Berkrot, *Gilead Put Profit Ahead of Hepatitus C Patients: U.S. Senate Report*, REUTERS

13. By preventing competition through manipulation of the patent system and the Hatch-Waxman provisions that encourage generic competition, Gilead is able to impose costs on AHF and the public by maintaining artificially high pricing for drugs containing TAF. The United States Senate Report on Gilead's pricing of another antiviral drug (Sovaldi) found, "Without successful competition, the costs to the public and private payers could have caused much more significant disruptions and access restrictions for years."[7]

14. AHF has been directly impacted by Gilead's scheme to maintain inflated pricing for drugs containing TAF. AHF has had to pay inflated pricing for Genvoya and anticipates that, because of a lack of generic competition and Gilead's blocking the market for generic entry through its invalid patents and anticompetitive practices, AHF will be forced to continue to pay exorbitant and unwarranted costs for years to come. AHF respectfully requests that the Court enter a declaration that United States Patent Nos. 7,390,791; 7,800,788; 8,754,065; 8,148,374; and 8,633,219 are invalid under 35 U.S.C. §§ 101 *et seq*. Further, AHF requests that the Court find the acts and conduct of Defendants unlawful violations of the Sherman Act.

II. THE PARTIES

A) AIDS Healthcare Foundation

15. Established in 1987, AHF is the largest non-profit provider of specialized HIV/AIDS medical care in the United States. AHF provides large-scale HIV counseling and testing services, early intervention services, HIV medical care, research on HIV care and treatment, medical case management, pharmacy services, referrals, and innovative client retention protocols.

16. AHF is a non-profit organization in Los Angeles, California, having a principal place of business at 6255 W. Sunset Boulevard, 21st floor, Los Angeles, California, 90028. AHF has 3,350 employees worldwide. AHF operates 46 Healthcare Centers in the United States spread

---

NEWS (December 1, 2015) (quoting Senator Ron Wyden); *Gilead Focused On Profit, Not Patients, Senate Report Concludes*, SFGate.com (December 1, 2015) ("The evidence shows the company pursued a calculated scheme for pricing and marketing its hepatitis C drug based on one primary goal — maximizing revenue — regardless of the human consequences").

[7] The Price of Sovaldi and Its Impact on the U.S. Health Care System at 120 (December 2015).

through 14 states and the District of Columbia. Worldwide, AHF has 575,000 patients and clients.

17. AHF also operates managed care programs for people living with HIV and/or AIDS. There are currently 4,700 individuals enrolled in its care plans.

18. AHF placed its first order for Genvoya on November 9, 2015. AHF primarily orders Genvoya from Cardinal Health. Cardinal is one of 25 Gilead Authorized Distributors of Record.[8] Gilead has shipped Genvoya and other HIV medication directly to a facility operated by AHF.

19. In 2015, AHF purchased millions of dollars of antiviral pharmaceutical drugs from Gilead.

20. On January 21, 2016, AHF sent a letter (attached as Exhibit A) to Dawn Dyna, Sr. Manager of Governmental Contracts at Gilead, "formally request[ing] that Gilead Sciences, Inc. [] permit our organization to purchase tenofovir alafenamide as a stand-alone product."

21. AHF has requested to place orders with pharmaceutical manufacturers to make a standalone TAF product. Because Gilead claims its patents cover TAF, these drug makers have refused to provide AHF with a standalone version of TAF. Gilead's prevention of the development of standalone TAF negatively affects AHF's patients and clients by preventing them from gaining access to TAF. Competitor pharmaceutical companies' entry into the market and/or provision of drugs containing TAF would put AHF at risk of liability as an indirect infringer of Gilead's patents covering TAF.

22. The long history of disputes between Gilead and AHF relating to antiviral drugs has given AHF a reasonable apprehension that it would face a patent infringement suit from Gilead were it to sell, import, develop, distribute, and/or test an unlicensed drug containing TAF. The parties have a history of disputes regarding the patents to HIV compounds. These disputes are likely to continue for the foreseeable future. AHF and Gilead thus have adverse legal interests over a dispute of sufficient reality that is capable of conclusive resolution through a declaratory judgment. The longstanding disputes between AHF and Gilead that provide AHF with a

[8] Authorized Distributors of Record, Gilead Website (last visited January 23, 2016), available at: http://www.gilead.com/medicines/authorized-distributors

reasonable apprehension of suit include: (1) In March 2008, AHF petitioned drug manufacturers including Gilead to freeze the price of their HIV drugs in the U.S. (2) AHF's January 2016 complaint against Gilead for Truvada PrEP ads promoting off-label use of Truvada. AHF filed a complaint with the FDA asking that Gilead be held accountable for promoting off-label use of Truvada. (3) A January 2014 dispute between AHF's President, Michael Weinstein, and Gilead regarding a shareholder proposal submitted to Gilead by Mr. Weinstein requesting that compensation for the chief executive officer should include non-financial measures based on patient access to Gilead's medicines. Mr. Weinstein proposed this resolution after Gilead's chief executive was paid 90 million dollars in 2013.[9] Gilead opposed the resolution and claimed it was "another tactic calculated to pressure the Company [Gilead]."). [10] (4) AHF's Freedom of Information Act lawsuit to release Gilead documents and testing information relating to Truvada.

23. AHF has a present intent to supply its clients in the United States with TAF drugs including unlicensed TAF drugs and a standalone TAF drug. AHF is prepared to distribute standalone TAF drugs through its network of pharmacies. In addition, AHF has sold Genvoya, which contains TAF obtained from Gilead, to its customers. Further, AHF is ready and immediately able to distribute a standalone version of TAF to its researchers.

24. Gilead has previously entered into pay-for-delay settlements with generic manufacturers. The risk that Gilead will reach a settlement with a generic to delay access is a real and immediate threat. Only through clearing the invalid patents that Gilead has obtained allegedly for TAF will AHF be able to ensure that there is generic entry.[11]

25. At bottom, AHF is in the position of either abandoning its plans and intent to obtain

---

[9] Martin Sasnoff, The Rapacious Enrichment of Gilead's CEO, Forbes Markets (April 1, 2014) ("Gilead's CEO John Martin took home more than $90 million making him one of the 10 highest paid CEO's in the country. His 5-year compensation exceeded $250 million.").

[10] Brett Pletcher, *Correspondence to the Securities and Exchange Commission* (February 4, 2014), available at: http://www.sec.gov/divisions/corpfin/cf-noaction/14a-8/2014/michaelweinstein022114-14a8.pdf.

[11] Based on a review of court filings it appears that Gilead was able to delay generic entry by reaching settlements in the following two cases. *Gilead Sciences, Inc., v. Teva Pharmaceuticals USA, Inc., et. al.* 1-10-cv-01796 (NYSD Foley Square) (Dkt. No. 128); *Gilead Sciences, Inc., v. CIPLA Limited,* NYSD-1-12-cv-06351 (Dkt. No. 76).

a standalone TAF product or run the risk of being sued for infringement, which is precisely the type of situation the Declaratory Judgment Act is intended to remedy.

26. Gilead's statements regarding its willingness to enforce its intellectual property rights has given AHF a reasonable apprehension that were it to continue its course of obtaining a standalone unlicensed version of TAF it would be subject to patent suit by Gilead. These statement include:

> Patents and other proprietary rights are very important to our business. If we have a properly drafted and enforceable patent, it can be more difficult for our competitors to use our technology to create competitive products and more difficult for our competitors to obtain a patent that prevents us from using technology we create. As part of our business strategy, we actively seek patent protection both in the United States and internationally and file additional patent applications, when appropriate, to cover improvements in our compounds, products and technology.[12]

> It is the policy of Gilead to enforce its intellectual property rights to the fullest extent permitted under law. Gilead Terms of Use.

> Further, Gilead in its License Agreement with Japan Tobacco agreed to investigate any alleged or threatened infringement and assist in the investigation and enforcement "pertaining to such infringement.[13]

27. Gilead has frequently filed suit to enforce its patent rights.[14] Gilead has alleged infringement against companies such as Teva based on its patents relating to Tenofovir.

28. Taken together, Gilead's activities thus demonstrate that it has engaged in a course of conduct that shows a preparedness and a willingness to enforce its patent rights.

B) Gilead

29. Defendant Gilead is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 333 Lakeside Drive, Foster City, California 94404.

30. Gilead is a biopharmaceutical company that develops and commercializes

---

[12] Gilead 10-K at 16 (2014).
[13] Third Amendment to License Agreement Between Japan Tobacco and Gilead Sciences § 3.16 (July 5, 2011).
[14] *See e.g., Gilead Sciences, Inc. et al v. Watson Laboratories, Inc*. NJD-1-15-cv-02350 (Filed April 3, 2015).

medicines. Its primary areas of focus include human immunodeficiency virus (HIV), liver diseases such as chronic hepatitis C virus (HCV) infection and chronic hepatitis B virus (HBV) infection, oncology and inflammation, and serious cardiovascular and respiratory conditions.

31. Sales of Gilead products, including sales related to HIV and liver diseases were $22.8 billion in 2014, $9.3 billion in 2013 and $8.1 billion in 2012. This represented 91% of Gilead's total revenues in 2014, 83% of Gilead's total revenues in 2013, and 84% of Gilead's total revenues in 2012. Gilead sales through the first three quarters of 2015 were an astonishing $23.7 billion putting them on pace for yearly sales of over $30 billion for the entire year.

32. Gilead notes in its SEC filings, one of the primary risks the company faces is that, "[a] substantial portion of [its] revenues is derived from sales of products to treat HCV and HIV. If [Gilead is] unable to maintain or continue increasing sales of these products, [the] results of operations may be adversely affected." In fact, for the year ended December 31, 2014, sales of its HIV products accounted for more than 40% of total product sales. Most of Gilead's HIV products contain tenofovir disoproxil fumarate and/or emtricitabine, which belong to the nucleoside class of antiviral medications.

33. Gilead publicly acknowledges that if the treatment paradigm for HIV changes, causing nucleoside-based therapeutics to fall out of favor, or if Gilead is unable to maintain or continue increasing its HIV product sales, Gilead's profits would suffer. Gilead acknowledged that it might not be able to sustain or increase the growth rate of sales of HIV products if generic HIV products are introduced into major markets because its ability to maintain pricing and market share may be affected. Gilead therefore has resorted to new patent strategies to stop generic HIV products from eroding its enormous profits.

34. Gilead's pricing is unrelated to its expenditures on Research and Development.

35. Gilead has litigated on patents relating to Tenofovir.

36. Gilead owns the following patents:

- U.S. Patent No. 7,390,791, entitled "Prodrugs of phosphonate nucleotide analogues."
- U.S. Patent No. 7,803,788, entitled "Prodrugs of phosphonate

nucoleotide analogues." [15]

U.S. Patent No. 8,148,374, entitled "Modulators of pharmacokinetic properties of therapeutics."

U.S. Patent No. 8,754,065, entitled "Tenofovir alafenamide hemifumarate."

C) Japan Tobacco Inc. & Japan Tobacco International U.S.A., Inc.

37. Defendant Japan Tobacco is a corporation organized under the laws of Japan, having a principal place of business at 2-1, Toranomon 2-chome, Minato-ku, Tokyo 105-8422.

38. Defendant Japan Tobacco International U.S.A., Inc. is a corporation organized under the laws of the State of California, having a principal place of business at 500 Frank W. Burr Boulevard, Suite 24, Teaneck, N.J.

39. Japan Tobacco and Japan Tobacco International U.S.A., Inc. (collectively, "Japan Tobacco") entered into a series of exclusive licensing agreements with Gilead relating to the compound elvitegravir.

> In 2005, we entered into a licensing agreement with Japan Tobacco, under which Japan Tobacco granted us ***exclusive rights to develop and commercialize elvitegravir***, a novel HIV integrase inhibitor, in all countries of the world, excluding Japan, where Japan Tobacco retains such rights.[16]
>
> The agreement and our obligation to pay royalties to Japan Tobacco will terminate on a product-by-product basis as patents providing exclusivity for the product expire or, if later, on the tenth anniversary of the commercial launch for such product.[17]

40. Japan Tobacco owns the following patents, which it has licensed to Gilead:

- U.S. Patent No. 7,176,220, entitled "4-oxoquinoline compound and use thereof as pharmaceutical agent."
- U.S. Patent No. 7,635,704, entitled "Stable crystal of 4-oxoquinoline compound."
- U.S. Patent No. 8,633,219, entitled "Combination therapy."
- U.S. Patent No. 8,981,103, entitled "Stable crystal of 4-oxoquinoline compound."

---

[15] The Orange Book incorrectly lists U.S. Patent No. 7,800,788, instead of 7,803,788.

[16] Gilead Sciences 10-K at 12 (2014) (emphasis added).

[17] Gilead Sciences 10-K at 12 (2014).

D) Emory University

41. Defendant Emory University ("Emory") is a non-profit corporation of the State of Georgia, having an office at 201 Dowman Drive, Atlanta, Georgia 30322.

42. Emory University entered into an exclusive licensing relationship with Gilead relating to patents held by Emory that relate generally to emtricitabine.

43. Emory owns the following patents, which it has exclusively licensed to Gilead:

- U.S. Patent No. 5,814,639, entitled "Method for the synthesis, compositions and use of 2'-deoxy-5-fluoro-3'-thiacytidine and related compounds".
- U.S. Patent No. 5,914,331, entitled "Antiviral activity and resolution of 2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane".
- U.S. Patent No. 6,642,245, entitled "Antiviral activity and resolution of 2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane".
- U.S. Patent No. 6,703,396, entitled "Method of resolution and antiviral activity of 1,3-oxathiolane nuclesoside enantiomers".

44. Emory has enforced its patent rights as a co-plaintiff with Gilead in several cases.[18]

III. JURISDICTION AND VENUE

45. This action arises under the Patent Laws of the United States of America, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction over the action under 28 U.S.C. § 1331, § 1337(a), and § 1338, based on Defendants' anticompetitive conduct, and the existence of an actual controversy between AHF, on the one hand, and Defendants, on the other hand, for claims under the Patent Laws. *See infra*.

46. This Court has personal jurisdiction over Defendants pursuant to the laws of the State of California, including California's long-arm statute, and California Code of Civil Procedure § 410.10. First, the Court has jurisdiction over Gilead which is, on information and belief, the direct owner of each of the Patents-in-Suit because Gilead maintains its principal place of business in this district and because Gilead is registered with the California Secretary of State to do business in California.

[18] See e.g., *Gilead Sciences, Inc., et al v. Lupin Limited*, NYSD-1-14-cv-05352 (Filed July 16, 2014).

47. The Court also has personal jurisdiction over each of the Defendants because each of the Defendants has purposely conducted its patent enforcement activities in this district and towards residents of this District. These enforcement activities include the signing of agreements regarding the exclusive licensing of patents that are orange book listed for Genvoya.

48. Venue is proper in this Court pursuant to 15 U.S.C. § 22 and 28 U.S.C. §§ 1391 and 1400 because Gilead resides in the Northern District of California and a substantial portion of the events giving rise to this action, including the development of the accused instrumentalities, took place here.

IV. REGULATORY BACKGROUND

49. Gilead uses patents of dubious validity to inflate the prices of a compound discovered over 31 years ago - well outside traditional patent protection.

50. Brand drug companies like Gilead often obtain valid patents that cover the new drug products. This process encourages research and development of new drugs by providing a time-limited period wherein the brand drug company is the only company that can distribute the new product.

51. This period of time (20 years) is limited to the statutory term of the patent covering the new drug. Once the patents expire, other companies are free to make their own versions of the same products, ushering in competition that lowers prices for consumers of the prescription drugs.

52. Given the high profits brand drug companies can reap while a drug is under patent protection, brand drug companies develop sophisticated patent prosecution strategies to try to maximize the time during which they are the sole distributors of the drug in question.

A) Brand Drug Company Patent Strategy

53. In many cases, the first group of patents covering a new brand drug reflect a genuine technological breakthrough that will provide the backbone of a new, safe, and effective drug. These initial patents typically cover the active compound in a prescription drug or a particular pharmaceutical composition.

54. With respect to TAF, the prodrug compound was not a breakthrough and should not have been patentable. At the time TAF was developed it was well known that formulating antiviral compounds as prodrugs allows intracellular absorption. Thus, substituting the disoproxil ester of Tenofovir with an aryl phosphoramidate ester would have been obvious. Similarly, the use of fumarate salt for formulation purposes would be obvious in light of TDF and the other considerable prior art on salt selections.

55. As the research and development process on the drug continues, a brand drug company will continue filing patent applications with the United States Patent and Trademark Office. However, the initial breakthrough is already in the prior art – either because the brand drug company has already filed a patent application on it or, like here, the brand drug company is working to commercialize previous scientific breakthroughs. Therefore, the follow-on patents prosecuted by brand drug companies are limited in scope. These follow-on patents can only be obtained for features of the drug that the brand drug company can show are non-obvious improvements over the growing body of prior art.

56. A typical patent portfolio for a brand drug has its most significant patent issuing first. The later follow-on patents are typically much weaker and more vulnerable to attack as invalid under either 35 U.S.C. §§ 102 and/or 103 as anticipated or obvious in view of older subject matter in the prior art. Many times the these follow-on patents merely claim methods of using compounds and formulations that are known in the prior art and are thus vulnerable to invalidation under 35 U.S.C. § 101 for claiming patent ineligible subject matter. These follow-on patents are also often easy to design around, and thus not infringed by competitors interested in entering the market.

57. While follow-on patents are often fairly weak, brand drug companies pour extensive resources into obtaining these patents because the later-issued patents extend the period of time their drugs are covered by unexpired patents. That is, because the follow-on patents are typically filed much later than the earlier patents, their expiration dates fall later than the expiration dates of the earlier patents. This strategy of continually filing follow-on patents is

commonly described as "ever-greening."

B) FDA Approval of New Drugs

58. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a brand drug manufacturer obtains FDA approval to market a new drug by filing a New Drug Application ("NDA").[19] The NDA process is a long and expensive process requiring multiple phases of clinical trials. It can take anywhere between 7-17 years to conduct the clinical trials necessary to obtain the scientific evidence necessary to obtain approval of an NDA.[20] Throughout the NDA process, the brand drug maker aims to provide the FDA with data establishing that the drug is safe and that it is effective in treating the conditions identified in the proposed labeling of the new drug.

C) FDA "Orange Book"

59. To place other drug makers on notice about potential proprietary patent claims for newly-approved drugs, a brand drug maker must identify to the FDA all patents it believes cover its new drug. The FDA publishes a list of those patents' corresponding brand drugs in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is commonly referred to as the "Orange Book."

60. Patents that are issued after the FDA approved an NDA for a new drug may be listed in the Orange Book within 30 days of a new patent's issuance.

61. Under FDA rules, the brand drug maker is only permitted to list patents that are "reasonably enforceable." However, there is no FDA review or oversight as to whether any particular listing of a patent corresponding to a brand drug is "reasonably enforceable" or appropriate. The FDA merely relies on the drug maker's truthfulness about patent validity and applicability. The FDA only performs a ministerial act in listing the patents identified by drug makers in the Orange Book.

[19] 21 U.S.C. §§ 301-392.

[20] *See, e.g.*, http://www.fdareview.org/approval_process.shtml

D) Approval Process for Generic Drugs

62. In 1984, Congress passed the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments were designed to speed introduction of low-cost generic drugs to market by permitting manufacturers of generic drugs to file an abbreviated new drug application ("ANDA"). The ANDA process allows the generic drug manufacturer to rely on the scientific data regarding safety and efficacy the brand drug maker submitted in its NDA. In the ANDA, a generic manufacturer need only show that the generic drug is pharmaceutically equivalent and bioequivalent to the brand drug.

63. Because the ANDA process does not require the multiple phases of clinical trials required by the NDA process, generic drug manufacturers can gain FDA approval to market a generic version of the brand drug much faster and less expensively than if they had to conduct their own clinical trials.

64. The purpose of the Hatch-Waxman Amendments was to speed the entry of safe and effective generic versions to market so that the public could enjoy the significant cost savings generated by competition in the market for a specific drug.

65. In addition to the streamlined ANDA process, the Hatch-Waxman Amendments created a mechanism to resolve patent disputes between brand and generic manufacturers before generic products launch. The Hatch-Waxman Amendments permit a brand manufacturer to sue a generic manufacturer for patent infringement even if the ANDA has not yet been approved and the generic version of the drug introduced on the market.

66. When a manufacturer files an ANDA application, the generic manufacturer must certify that the proposed generic drug will not infringe any valid patent listed for the brand drug in the Orange Book. The generic manufacturer can make one of four certifications: (i) that no patent for the brand drug has been filed with the FDA; (ii) that the patent for the brand drug has expired; (iii) that the patent for the brand drug will expire on a particular date and the generic company does not seek to market its generic product before that date; or (iv) that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product

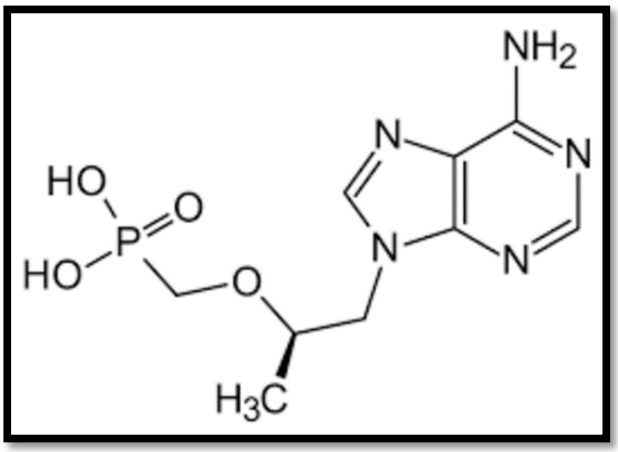
(a "Paragraph IV certification").

67. If a generic manufacturer files a Paragraph IV certification, a brand drug maker can sue the ANDA applicant for patent infringement immediately – the brand drug maker does not need to wait for the generic version of the drug to enter the market. If the brand drug maker files an infringement action against the ANDA applicant within 45 days of receiving notification of the Paragraph IV certification ("Hatch-Waxman Litigation"), the FDA cannot grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the entry of a final judgment on a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA will not authorize the generic manufacturer to market its generic drug.

V. FACTUAL ALLEGATIONS

A) The Development Of Tenofovir

68. Tenofovir was first discovered more than three decades ago by researchers in the Czech Republic. Tenofovir was initially synthesized by Antonín Holý at the Institute of Organic Chemistry and Biochemistry, Academy of Sciences of the Czech Republic in Prague. From early on, it was clear that tenofovir exhibited anti-HIV effects. However, the initial form of tenofovir used in these studies had limited potential for widespread use because it was not absorbed when administered orally.



Tenofovir Molecular Structure.

69. In 1997, Gilead obtained a patent on a prodrug formulation of tenofovir that

allowed absorption of tenofovir in the gut. The formulation of prodrugs was well known at the time as was the anti-HIV effectiveness of tenofovir. By combining the known technique "ProDrug Formulation" to an existing compound with anti-HIV properties, tenofovir disoproxil (TDF) was developed.

70. The patent application filed by Gilead on tenofovir was originally rejected on obviousness grounds – both compounds were known, as was the fact that conversion of a compound to its salt could enhance activity. Unless it could be shown that the salt possessed unexpected properties, it was unpatentable. The applicant replied that the salt did indeed possess unexpected properties – it had greater stability at higher humidity and temperature levels. On this basis, a patent was granted in August 1999. This history underscores the dubious nature of the prodrug patents on tenofovir.

71. TDF was approved by the U.S. FDA on October 26, 2001, for the treatment of HIV.

1) Gilead Patents Another ProDrug Formulation Of Tenofovir - Tenofavir Alafenamide (TAF)

72. GS-7340, or TAF, is a prodrug of tenofovir. TAF is taken orally and after absorption, it passes into the blood. From the blood, TAF is absorbed by cells of the immune system and converted into tenofovir.

73. The purported inventive step in TAF appears to be the simple process of combing well known techniques in prodrug formulation with the tenofovir compound that had been known for over a decade as having anti-HIV effects.

74. Commentators reviewing the TAF patents have found them weak. .Doctors Without Borders, in its publication, explained, "The main patent is potentially weak and can be opposed in countries where patent opposition systems are functional."[21]

75. Instead of developing a standalone drug product, Gilead, based on the weakness of the patents on TAF, went forward with a pharmaceutical drug product combining four active

[21] Medecins Sans Frontieres July 2013 https://www.msfaccess.org/sites/default/files/AIDS_Report_UTW16_ENG_2013.pdf

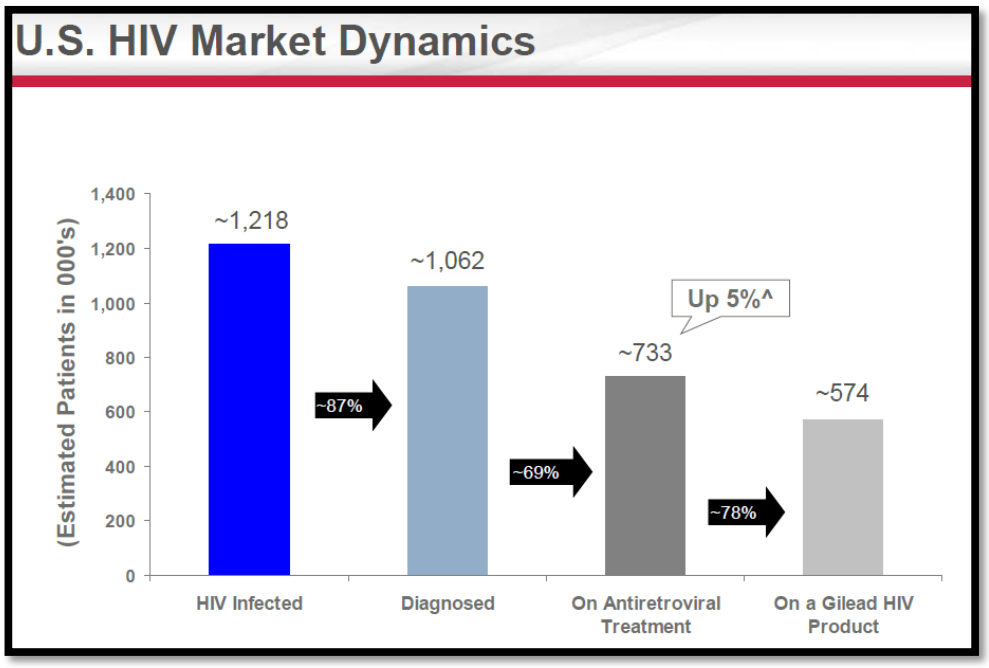
ingredients: 150mg cobicistat, 150mg elvitegravir, 200mg emtricitabine and EQ 10mg base tenofovir alafenamide fumerate. Three of these active ingredients were licensed by Gilead from third parties. By bundling TAF into a combination product with other patentable active ingredients, Gilead was able to list twelve patents as covering the combined drug formulation in the Orange Book. The below image shows the Orange Book listed patents for this combined drug – Genvoya.

Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code
N207561	001	5814639	Sep 29, 2015	Y	Y	
N207561	001	5814639*PED	Mar 29, 2017			
N207561	001	5914331	Jul 2, 2017	Y		
N207561	001	5914331*PED	Jan 2, 2018			
N207561	001	6642245	Nov 4, 2020			U - 257
N207561	001	6642245*PED	May 4, 2021			
N207561	001	6703396	Mar 9, 2021	Y	Y	
N207561	001	7176220	Nov 20, 2023	Y	Y	U - 257
N207561	001	7390791	May 7, 2022	Y	Y	
N207561	001	7635704	Oct 26, 2026	Y	Y	U - 257
N207561	001	7800788	Feb 2, 2022			U - 257
N207561	001	8148374	Sep 3, 2029	Y	Y	U - 1279
N207561	001	8633219	Apr 24, 2030		Y	U - 257
N207561	001	8754065	Aug 15, 2032	Y	Y	U - 257
N207561	001	8981103	Oct 26, 2026	Y	Y	

76. The techniques Gilead undertook to transform the base tenofovir compound into an end formulation were obvious in light of existing literature and knowledge on how to formulate poorly bioavailable nucleotide analogs.

77. A core goal of Gilead is to move HIV infected individuals onto its Gilead HIV Products. The below chart from Gilead's most recent earnings release shows the process of moving individuals diagnosed with HIV to a Gilead Product.



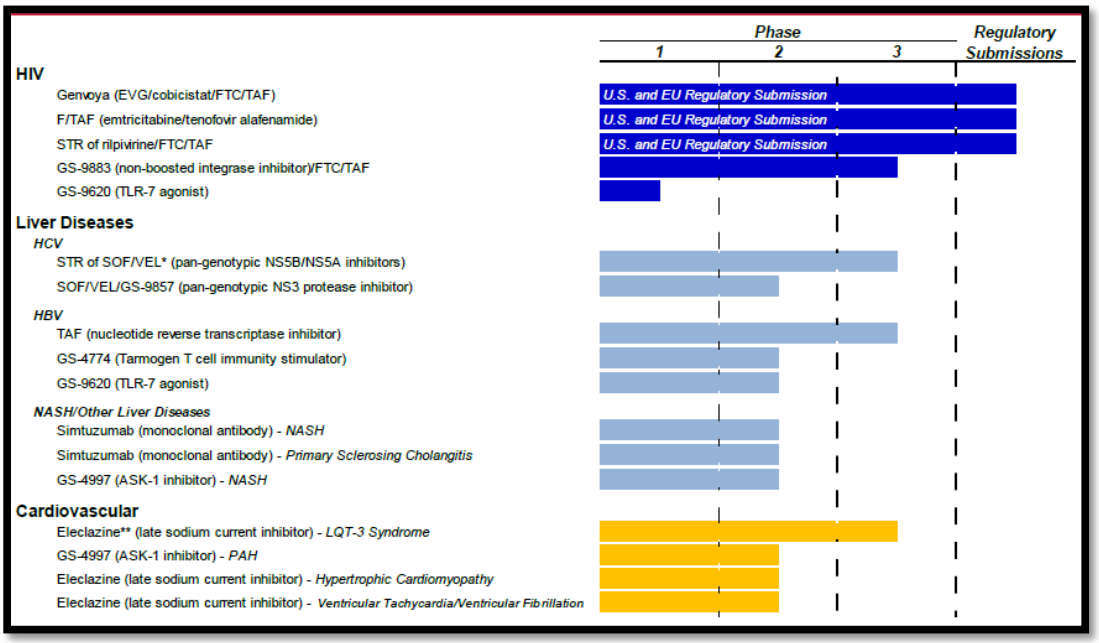
GILEAD 2015 THIRD QUART EARNINGS SLIDES at 29 (2015).

78. The co-formulation of Genvoya blocks lower priced generic entry and artificially inflates pricing. Analysts have confirmed that the failure to provide a standalone product harms the public.

> Innovator companies must ensure that novel compounds are studied and made available on the market as single pills as well as in fixed-dose combinations (FDCs) to enable people with HIV to assemble optimal combinations based on their own needs. Thus, Gilead needs to ensure that elvitegravir, cobicistat, and – when available – tenofovir alafenamide (TAF) are each available as single pills to maximize patient and provider choice. This is particularly critical for TAF.[22]

79. Despite this harm from releasing only combination drugs, Gilead has only combination drugs in its pipeline for drugs incorporating TAF.

[22] 2013 Pipeline Report at 40 (June 2013) (Report published by HIV advocacy organizations HIV i-Base and Treatment Action Group).



Gilead Third Quart Earnings Slides at 6 (October 27 2015) (Four of five Gilead HIV Drugs that are in the pipeline are combination drugs that include TAF).

2) Artificially High Pricing For Drugs Such As Genvoya Harms The Public And Allows Gilead To Wrongfully Reap Billions In Profit.

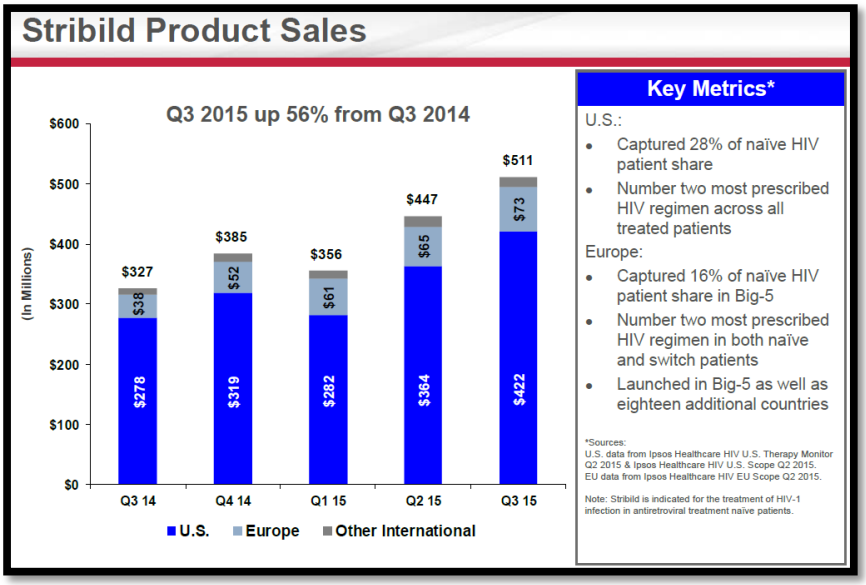
80. In stark contrast to the wealth of Gilead, people living with HIV and AIDS (those most desperately in need of Gilead's medications) are among the poorest and most vulnerable in the United States. Gay, bisexual, and other men who have sex with men (MSM) of all races and ethnicities remain the population most profoundly affected by HIV. Although MSM represent about 4% of the male population in the United States, in 2010, MSM accounted for 78% of new HIV infections among males and 63% of all new infections. MSM accounted for 54% of all people living with HIV infection in 2011, the most recent year these data are available.

81. Moreover, African Americans continue to experience the most severe burden of HIV compared with other races and ethnicities while Hispanics/Latinos are also disproportionately affected by HIV. African Americans, who make up just 12% of the population, account for 44% of new infections.

82. Economic status often determines access to HIV treatment and individuals with low status have delayed treatment initiation relative to more affluent patients, reducing their chances of survival. Nearly 90% of Ryan White HIV/AIDS Program clients – clients receiving

federal funds for HIV/AIDS care and treatment – have a household income of less than 200% of the Federal Poverty Level (about $23,000). Despite the link among income/HIV status/access to treatment, Gilead continues to put profits ahead of patients.

83. Gilead's Stribild Product Sales were over one billion dollars in the first three quarters of 2015.



GILEAD 2015 THIRD QUART EARNINGS SLIDES at 32 (2015).

84. Through its patent schemes, Gilead is able to earn outsized profit margins. For example, in the third quarter of 2015 Gilead's Non-GAAP Product Gross Margin was nearly 90%. This money is paid by organizations such as AHF that are harmed by invalid patents that artificially prop up the pricing of branded drugs like Genvoya.

85. Gilead's tactics themselves harm AHF. For example, Gilead refuses to release a standalone version of TAF and thus prevents AHF from providing efficient treatment options that are tailored to its patients. The World Health Organization has identified Gilead's tactic as harmful.

> TAF is being co-formulated with emtricitabine (FTC), elvitegravir and cobicistat and is being trialled in phase III now. In order for TAF to reach its full impact,

> registration that includes flexibility in its use and ability to be combined with other ARVs is required. As such, TAF should be registered as a single drug.[23]

86. AHF Research has nearly 20 years of experience with anti-retroviral (ARV) studies and is dedicated to discovering better treatments and improving quality of life for people living with HIV. However, by preventing AHF from studying the efficacy of a standalone version of TAF, Gilead harms AHF's research endeavors.

87. AHF's Pharmacies have been directly harmed by Gilead's patent thicket. AHF operates 37 Pharmacies in 11 states. AHF Pharmacies include locations in this District: 4071 18th St., San Francisco, CA 94114 and 400 30th St. Suite 300, Oakland, CA 94609. Granting access to TAF directly will lead to a direct increase in access to drugs. Indeed, following widespread pressure from groups taking issue with Gilead's prior activities relating to drug pricing, Gilead granted the Medicines Patent Pool (MPP) the "right to sub-license TAF to generic drug companies who manufacture and distribute in 112 developing countries."[24]

B) Gilead's Scheme To Block Competition And Monopolize The Market For TAF.

1) Monopoly Power And Market Definition.

88. At all relevant times, Gilead has maintained monopoly power over tenofovir alafenamide ("TAF") in that it has the power to maintain the price of TAF at supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable.

89. Direct proof exists that Gilead has monopoly power over the price of TAF. Such direct evidence includes, among other things, the abnormally high price margins enjoyed by Gilead and Gilead's ability to profitably maintain the price of TAF well above competitive levels.

90. To the extent Plaintiff is legally required to prove monopoly power circumstantially by first defining a relevant product market, the relevant product market is all TAF-containing products. The relevant geographic market is the United States and its territories.

91. A small but significant non-transitory price increase above the competitive level

---

[23] Untangling the Web of ARV Price Reductions, World Health organization at 17, https://www.msfaccess.org/sites/default/files/MSF_UTW_17th_Edition_4_b.pdf.

[24] Gilead 2015 Third Quarter Slides at 48 (2015).

for TAF by Gilead would not cause a loss of sales sufficient to make the price increase unprofitable.

92. At competitive price levels, TAF does not exhibit significant positive cross-elasticity of demand with respect to price with any other products.

93. TAF's pharmacological profile, and thus its side effects and efficacy profile, is different from other medicines used to treat the same or similar conditions. For example, TAF has lower incidence of impaired kidney function than tenofovir disoproxil. These differences play a critical role in doctors' selection of the most appropriate treatment for patients. Other, non-TAF-containing medicines cannot be automatically substituted for the only TAF-containing product (Genvoya) on the market by pharmacists. Other medicines do not exhibit substantial cross-price elasticity of demand with respect to TAF, and thus are not economic substitutes for, nor reasonably interchangeable with, TAF.

94. The existence of other products designed to treat HIV have not significantly constrained Gilead's pricing of Genvoya (its only TAF-containing product in the relevant market). Gilead has never lowered the price of Genvoya in response to the pricing of other branded treatments.

95. Gilead needed to control only Genvoya, and no other products, in order to maintain the price of TAF profitably at supracompetitive prices. Only the market entry of a generic version of Genvoya or a competing TAF stand-alone product would render Gilead unable to profitably maintain its current prices of Genvoya without losing substantial sales.

96. Gilead has maintained and exercised the power to exclude and restrict competition to TAF.

97. At all relevant times, Gilead's market share in the relevant market was and remains 100%, constituting substantial monopoly power.

2) Interstate Commerce.

98. At all material times, Gilead manufactured, promoted, distributed, and sold substantial amounts of TAF in continuous and uninterrupted flow of commerce across state and

national lines and throughout the United States.

99. At all material times, Gilead transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of TAF.

100. In furtherance of its efforts to monopolize and restrain competition in the market for TAF, Gilead employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. The activities of Gilead were within the flow and have substantially affected interstate commerce.

3) Effects On Competition.

101. Typically, generic versions of brand drugs are initially priced significantly below the corresponding brand drug. As a result, upon generic entry, purchases of brand drugs are rapidly substituted by purchases of generic versions of that drug. As more generic manufacturers enter the market, prices for generic versions of a drug plunge even further because of the competition among the generic manufacturers, and the brand drug continues to lose even more market share to the generics.

102. This price competition enables purchasers to purchase generic versions of a drug at a substantially lower price, and/or purchase the brand drug at a reduced price. Therefore, brand drug manufacturers have a significant financial interest in delaying the onset of generic competition, and patients experience substantial cost inflation from that delay.

103. Gilead's ongoing anticompetitive scheme as alleged above will allow it to unlawfully maintain a monopoly and exclude competition in the market for TAF. But for Gilead's ongoing anticompetitive scheme to delay generic TAF competition in the United States, competing drug manufacturers would introduce competing TAF-containing products in the United States.

104. Gilead implemented its unlawful scheme by (1) unlawfully bundling TAF with elvitegravir, cobicistat, and emtricitabine, and (2) conspiring with Japan Tobacco and Emory to tie sales of TAF with elvitegravir, cobicistat, and emtricitabine in an effort to obtain and share

monopoly profits on the sale of TAF. These acts, in combination and individually, were anticompetitive.

105. But for the anticompetitive, illegal, and ongoing conduct alleged in this complaint, Plaintiff would begin paying less for TAF due to the entrants of competitors in the market for TAF and TAF-containing products.

106. Gilead, by its anticompetitive conduct, threatens to injure Plaintiff by causing it to pay hundreds of millions of dollars in overcharges on its purchases of Genvoya.

107. Defendants' unlawful conduct deprived AHF the benefits of competition that the antitrust laws were designed to protect.

COUNT I
DECLARATORY JUDGMENT OF INVALIDITY
(THE '791, '788, '065, '374, AND '219 PATENTS)

108. The above paragraphs are incorporated herein as set forth above.

109. Upon information and belief, Gilead is the current assignee of the '791, '788, '065, '374, and '219 Patents (collectively, the "TAF Patents").

110. As set forth above, an actual and justiciable controversy exists between AHF and Defendants as to whether the TAF Patents are valid.

111. The TAF Patents are invalid at least because they fail to comply with the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. § 101.

112. The TAF Patents are invalid at least because they are directed to abstract ideas and lack an inventive concept sufficient to transform the claims into a patent-eligible invention under 35 U.S.C. § 101. More specifically, '791, '788, and '065 patents are directed to the abstract idea of using a prodrug of a known compound. And, there is nothing in the claims which would act as an inventive concept sufficient to transform them into patent eligible subject matter.

113. The TAF patents are also invalid in view of extensive prior art that would render them obvious to one skilled in the art. For example, '219 patent claims methods of treating HIV by administering to a patient a triple-drug combination that contain elvitegravir, emtricitabine and

tenofovir fumerates. However, those drugs and their use for treating HIV was known and combination therapy to treat HIV was routine. Thus, the claims amount to nothing more than instructions to apply the abstract idea of combination therapy to known HIV drugs. As such, the claims are invalid for being ineligible subject matter.

114. The '374 patent is also invalid as prior art exists that anticipates or renders obvious each of their claims. The '374 patent claims cobicistat, and pharmaceutical compositions containing the cobicistat, that is useful in improving the pharmacokinetics of a co-administered drug. Specifically, cobicistat inhibits cytochrome P450 monooxygenase in a patient so that the pharmacokinetic profile of a co-administered therapeutic agent, such as an HIV drug, is improved. Co-administrating HIV drugs with other active agents that improve the pharmacokinetic profile of the HIV drug was not a new idea when the cobicistat patent application was first filed in 2007. It was known at that time that cytochrome P450 enzymes metabolize drugs and that the blood plasma levels of drugs which are susceptible to cytochrome P450 enzyme degradation can be maintained or enhanced by co-administration of cytochrome P450 inhibitors, thereby improving the pharmacokinetics of the drug. Many drugs were already known to inhibit cytochrome P450 enzymes, but there was a motivation to find more or improved inhibitors for cytochrome P450 monooxygenase because it was desired to have cytochrome P450 monooxygenase inhibitors that do not have appreciable biological activity other than cytochrome P450 inhibition. Such inhibitors were sought because they would be useful for minimizing undesirable side effects. In addition, it was desirable to have P450 monooxygenase inhibitors that lack significant or have a reduced level of protease inhibitor activity because such inhibitors could be useful for enhancing the effectiveness of antiretroviral drugs while minimizing the possibility of eliciting viral resistance, especially against protease inhibitors. Thus, there was a substantial motivation to develop new cytochrome P450 monooxygenase inhibitor compounds for particular use with HIV drugs and this motivation combined with the known P450 monooxygenase inhibitors already available would guide one towards the specific compound patented as cobicistat.

115. AHF is entitled to judgment declaring that TAF Patents are invalid because they

are directed to patent-ineligible subject matter under 35 U.S.C. § 101.

COUNT II
GILEAD'S ILLEGAL MONOPOLIZATION
(VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2)

116. Plaintiff incorporates by reference the allegations above, as if fully set forth herein.

117. As described above, at all relevant times, Gilead possessed monopoly power in the relevant market – the market for sales of TAF in the United States. But for Gilead's wrongful conduct, as alleged herein, Gilead would lose its monopoly power in the relevant market.

118. Gilead knowingly, willfully, and wrongfully maintained its monopoly power by improperly bundling TAF with elvitegravir, cobicistat, and emtricitabine to ensure that it can maintain monopoly prices on TAF.

119. Gilead knew that by bundling TAF with elvitegravir, cobicistat, and emtricitabine, rather than researching and seeking approval on standalone TAF, which is similar to its other standalone tenofovir TDF product (Viread), Gilead could maintain its monopoly pricing on TAF until the shorter of: (1) a competitor completing clinical trials and FDA review of an NDA on a standalone TAF product, (2) all 12 Orange Book listed patents for Genvoya expiring, which will not occur until at least the year 2032, or (3) a competitor filing a Paragraph IV certification on all 12 Orange Book listed patents for Genvoya and the ensuing litigation. Any one of these three periods of time is significantly longer than the period of time it would have taken a generic drug manufacturer to file a Paragraph IV challenge and for any resulting Hatch-Waxman Litigation to have occurred on just the TAF Patents, which could have happened had Gilead released a standalone TAF product.

120. Gilead knew that, by combining TAF with elvitegravir, cobicistat, and emtricitabine, it would reap monopoly profits during this significant difference in time. Further, Gilead knew and intended to deter potential market entrants by creating expensive and time-consuming barriers to entry resulting from the bundling of TAF with elvitegravir, cobicistat, and emtricitabine specifically to create and maintain monopoly profits on the sale of TAF.

121. Without creating these expensive and time-consuming barriers to entry, Gilead

would have enjoyed monopoly profits on TAF only for the period of time it took a generic drug manufacturer to prepare and file an ANDA, and the resulting Hatch-Waxman Litigation process. That period of time would be far less than any of the periods of time Gilead ensured by solely releasing TAF as a bundled product with elvitegravir, cobicistat, and emtricitabine.

122. Gilead's knowingly and intentionally bundled TAF with elvitegravir, cobicistat, and emtricitabine in an anticompetitive scheme deliberately designed to block and delay entry of competing versions of TAF to maintain its monopoly power.

COUNT III
CONSPIRACY AND AGREEMENT IN RESTRAINT OF TRADE
(IN VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1)

123. On information and belief, Defendant Emory and Defendant Gilead entered into an exclusive license agreement for patents relating to emtricitabine. To date, Emory has received at least $525 million in connection with this exclusive license.

124. On information and belief, Defendant Japan Tobacco and Defendant Gilead entered into an exclusive license agreement for patents relating to elvitegravir.

125. On information and belief, Japan Tobacco has received between $15-90 million, plus royalties on the sale of products, including Genvoya, containing elvitegravir.

126. On information and belief, Defendants Emory and Japan Tobacco knew or should have known that their exclusive licenses of patents to emtricitabine and elvitegravir, respectively, were to be used in a conspiracy to reap monopoly profits on tenofovir, and in particular, TAF.

127. Despite this knowledge, Emory and Japan Tobacco entered into an agreement and conspiracy with Gilead to license patents covering emtricitabine and elvitegravir with the knowledge and intent that Gilead would use those patents to erect barriers to entry that would create and maintain unjustified monopoly profits on the sale of TAF, and that Defendants Emory and Japan Tobacco would receive substantial payments for their part in this conspiracy to maintain monopoly profits on TAF.

128. Defendants' acts and conduct are a *per se* or a rule of reason violation of Section 1 of the Sherman Act.

129. Defendants' acts and conduct constitute an agreement, conspiracy, or combination between two or more entities or persons to restrain trade. Defendants' illegal conduct resulted in Plaintiff paying higher prices on TAF than it otherwise would have absent Defendants' conduct.

130. For at least the reasons discussed above, the agreement, conspiracy, or combination between Defendants is an unreasonable restraint of trade in the relevant product market of TAF under either a *per se* or rule of reason analysis.

131. Defendants' acts and conduct are harmful to and substantially burden competition, including but not limited to, increasing the price paid by Plaintiff for TAF.

132. The restraint that Defendants impose is not justified by any legitimate business purpose.

133. Defendants' unlawful conduct constitutes a contract, combination, or conspiracy and an unreasonable restraint of trade, in violation of the Sherman Act, 15 U.S.C. § 1.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully asks the Court to:

a) Declare that each claim of each patent in suit is invalid;

b) Enter judgment declaring the acts and conduct of Defendants as an unlawful violation of the Sherman Act;

c) Enter judgment requiring Defendants to pay AHF the monetary damages resulting from the unlawful violations and that those damages be trebled as provided by law;

d) Enter judgment requiring Defendants to pay automatically the attorneys' fees and costs incurred by AHF in bringing these claims as provided by law;

e) Award AHF such other and further relief as this Court may deem just and proper.

f) Issue a declaration under 28 U.S.C. § 2201 that the TAF Patents are invalid;

g) Issue an injunction enjoining Defendants and their agents, representatives, attorneys, employees, and those persons in active concert or participation with them who receive actual notice here from threatening or initiating infringement litigation against AHF or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors or customers of AHF, or charging them either orally in writing with infringement of the Patents-in-Suit;

h) Grant such other and further relief as the Court deems just.

JURY TRIAL DEMANDED

Plaintiff demands a trial by jury of all issues triable.

Dated: January 26, 2016

Respectfully submitted,

/s/ Dorian S. Berger

Dorian S. Berger (CA SB No. 264424)
Daniel P. Hipskind (CA SB No. 266763)
1880 Century Park East, Ste. 815
Los Angeles, CA 90067
Telephone: 213-516-7900
Facsimile: 213-516-7910
E-mail: dhipskind@olavidunne.com
E-mail: dberger@olavidunne.com

Tom Myers, CA State Bar No. 176008
Arti L. Bhimani, CA State Bar No. 235240
Liza M. Brereton, CA State Bar No. 261380
AIDS HEALTHCARE FOUNDATION
6255 W. Sunset Blvd., 21st Fl.
Los Angeles, California 90028
Telephone: 323-860-5200
Facsimile: 323-467-8450
Email: Tom.Myers@aidshealth.org
Email: Arti.Bhimani@aidshealth.org
Email: Liza.Brereton@aidshealth.org

Attorneys for Plaintiff AIDS Healthcare Foundation, Inc.